REMARKS

Claims 1-26 are pending in the present application. The Examiner requires election in the present application between:

Group I, claim 1, drawn to nucleic acid based vaccine;

Group II, claims 2-9, 16-21, and 25, drawn to antibodies and immunoglobulins that bind to Lewis B adhesin protein;

Group III, claims 10-15, drawn to a method of manufacturing an immunoglobulin or antibody;

Group IV, claims 22-24, drawn to a method of a method for treating and/or preventing *Helicobacter pylori* infections; and

Group V, claim 26, also drawn to a method for treating and/or preventing *Helicobacter pylori* infections.

For the purpose of examination of the present application, Applicants elect, with traverse, Group II, claims 2-9, 16-21, and 25.

With regard to Group II, the Examiner requires election between:

Species (a), drawn to polyclonal antibodies obtained from milk, colostrums, or egg yolks, or sera from a mammal, encompassed by claims 3-8 and 16-21;

Species (b), drawn to monoclonal antibodies obtained through fusion of antibody producing cells with a neoplastic cell line; and

Species (c), drawn to recombinantly produced antibodies contained in a transformed microorganism that is not a neoplastic

cell line, wherein the microorganism has been transformed with the genetic material that encodes the antigen-binding region of the monoclonal antibody.

For the purpose of initial examination of the present application, Applicants elect Species (a) with traverse. Claim(s) 3-8 and 16-21 are directed to the elected species. Applicants submit that at least claim 6 is generic.

Restriction Requirement

Applicants respectfully submit that the Examiner has issued an improper Restriction Requirement. In restricting Groups I-II and IV-V, the Examiner uses form paragraph 8.20.02, which is intended for use in restricting "unrelated inventions." Inventions are unrelated "where they are not connected in design, operation, or effect under the disclosure of the particular application under consideration." U.S. Pat. & Trademark Off., *Manual Pat. Examining Proc.* § 808.01 (8th ed., rev. 2 2004).

MPEP § 808.01 states that when using the "unrelated" rationale as a basis for requiring restriction, "*the facts relied on for this conclusion are in essence the reasons for insisting upon restriction.* This situation, except for species, is but rarely presented, since persons will seldom file an application containing disclosures of independent things (emphasis in original)." Further, the "Examiner Note" for this form paragraph states, "This form

paragraph is to be used only when claims are presented to unrelated inventions, e.g., a necktie and a locomotive bearing." *Id.*

In restricting Groups I-II and IV-V from one another, respectively, the Examiner utilizes an improper standard for "unrelatedness." Specifically, the Examiner asserts that Groups I and II are unrelated because they "do not share the same structural and functional characteristics, thus setting forth independent and distinct compositions…." The Examiner asserts that Groups IV and V are unrelated because "the antibodies of Group IV evidence different modes of operation, different functions and different effects from recombinantly transformed microorganisms of Group V, wherein the recombinantly transformed microorganisms of Group V comprise a coding sequence for a blood group binding antigen and the recombinant microorganism of Group IV encodes a protein antibody that binds to antigen…."

Applicants respectfully disagree with the Examiner's characterizations of the claims of the present invention. The claims of Groups I and II are related as nucleotide sequences and antibodies useful in vaccines and pharmaceutical compositions for the treatment and prevention of pathologic infections caused by *Helicobacter pylori* strains. Specifically, claim 1 of Group I is drawn to the vaccine and claims 2-9, 16-21, and 25 of Group II are related as antibodies, immunoglobulin compositions, and monospecific antisera, a pharmaceutical product/composition

comprising the antibodies and immunoglobulin compositions, and expression systems expressing said antibodies. Further, the antibody and immunoglobulin compositions of Group II are exhibit specific activity to Lewis^b binding adhesion protein or fractions thereof, which are expressed by *Helicobacter pylori*. Administration of the vaccines or antibody and immunoglobulin compositions treats and/or prevents *H. pylori* infections in humans in need thereof.

Similarly, the claims of IV and V are related as methods for treating or preventing *H. pylori* infections in a human. Both the antibody/immunoglobulin compositions exhibit specific activity to Lewis^b binding adhesion protein or fractions thereof, which are expressed by *Helicobacter pylori*. Further, the culture of viable microorganisms recited in claim 26 is genetically modified to express the Lewis^b binding adhesion protein. Therefore, the claims of Groups IV and V are related as to Lewis^b binding adhesion protein or fractions thereof.

For these reasons, the Examiner's assertion that Groups I-II and IV-V are unrelated because of alleged structural and functional differences is simply the improper standard for "unrelatedness." The expression of protein from nucleic acids and use of said proteins is so fundamental to the biotechnology industry that it cannot be reasonably characterized as "unrelated" in the same sense that a necktie and a locomotive ball bearing are unrelated.

Accordingly, the restriction is improper because all of the claims of Groups I-II and IV-V relate are clearly not "unrelated" within the meaning of MPEP § 808.01. Withdrawal of the instant restriction requirement and rejoinder of the claims is therefore respectfully requested.

The Examiner asserts that the claims of Group II and Group III are distinct because the products of Group II (i.e., immunoglobulin composition and antibodies which exhibit specific activity to Lewis^b binding adhesion protein or fractions thereof) can be "produced synthetically based upon biochemical synthesis of the antibodies from knowledge of the amino acid sequence that code the hypervariable antigen binding region of the antibodies/monospecific antisera." Again, Applicants respectfully submit that the Examiner has relied on a wrong standard for distinctness and consequently mischaracterized the present invention.

As noted above, claims 2-9, 16-21, and 25 of Group II are related as antibodies, immunoglobulin compositions, and monospecific antisera, a pharmaceutical product/composition comprising the antibodies and immunoglobulin compositions, and expression systems expressing said antibodies. Claims 10-15 of Group III are methods of manufacturing said immunoglobulin compositions or antibodies of Group II. The broadest claims of Group II are not limited by amino acid sequences. Rather, the antisera, immunoglobulin compositions, and antibodies are specific

for Lewis^b binding adhesion protein or fractions thereof. Thus, the Examiner's assertion that the antibodies etc. could be produced biochemically based on known sequences is incorrect. Accordingly, withdrawal of the instant restriction requirement and rejoinder of the claims is therefore respectfully requested.

Finally, in restricting the claims of Groups I-V, the Examiner asserts that Groups I-V are distinct because the "nucleotide sequence of claim 1 can be used in a method of making a protein…." Applicants point out that claim 1 is directed to a vaccine. Therefore, the Examiner's alternative use is not viable.

Based upon the above reasons, the Examiner is respectfully requested to withdraw the instant restriction requirement and rejoin at least the claims of Groups I, II, and III, and the claims of Groups IV and V.

Election of Species Requirement

In restricting the three alleged species of Group II from one another, the Examiner asserts that the monoclonal antibody recited in claim 9 and classified as species (b) is distinct from species (a) and (c) because the antibody therein is "obtained through fusion of antibody producing cell with a neoplastic cell line." Similarly, the Examiner asserts that the subject matter of claim 9 classified as species (c) is distinct from species (a) and (b) because the microorganism therein "has been transformed with the

genetic material that encodes the antigen-binding region of the monoclonal antibody."

Again, the Examiner has mischaracterized the claims. Claim 9 (species (b)) is actually dependent upon claim 6, which the Examiner classifies in species (a). Claim 6 recites an antibody which is specific to Lewis^b binding adhesion protein or fractions thereof. As such, claim 6 is not limited as to polyclonal or monoclonal structure. Claim 9 further limits claim 6 in defining the antibody of claim 6 as monoclonal. There is no limit in claim 9 as to the monoclonal antibody being produced through fusion of antibody producing cell with a neoplastic cell line. Similarly, claim 25 (species (c)) is dependent upon claims 8 and 9, which in turn are ultimately dependent upon claim 6. Claim 6 recites an antibody which is specific to Lewis^b binding adhesion protein or fractions thereof. Claim 25 recites microorganisms which are genetically modified to express the antibody of, ultimately, claim 6.

Since the Examiner's rational for restriction of species is clearly incorrect, the restriction is improper and should be withdrawn. At the very least, the Examiner is respectfully requested to acknowledge that claim 6 is generic for species (a)-(c), and to consider claims 9 and 25 as provided by 37 C.F.R. § 1.141.

Conclusion

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kristi L. Rupert (Reg. No. 45,702) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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